

Alexander S. Mathews
President and CEO

September 13, 2004

Division of Dockets Management
U.S. Food and Drug Administration
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

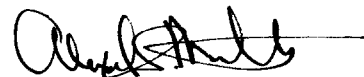
Re: Docket No. 2004D-0283 – Draft Guidance for Industry: Waivers of *In Vivo*
Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral
Dosage Form Products and Type A Medicated Articles

The ANIMAL HEALTH INSTITUTE (“AHI”) requests a 60-day extension of the comment period for Docket No. 2004D-0283 – Draft Guidance for Industry: Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles published by FDA in the *Federal Register* on August 3, 2004.

AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

Due to the potential impact on our industry of this proposed change, we request additional time to thoroughly review the document, analyze the impact on our industry and provide comments to the Docket. We appreciate your consideration of our request.

Sincerely,


Alexander S. Mathews

2004D-0283

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